AN EVALUATION OF THE EFFECTIVENESS OF A VIBRATING SYRINGE ATTACHMENT IN DECREASING INTRAORAL INJECTION PAIN PERCEPTION

by

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CERTIFICATE OF APPROVAL

MASTER'S THESIS

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ABSTRACT

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Introduction: Dental anxiety and fear of dental treatment are two primary reasons people avoid the dentist. Many people are anxious of the dental injection itself. Several devices have been manufactured to aid in the reduction of pain perception with the dental injection. One such device is the VibraJect®, which, according to manufacturer claims, decreases pain perception during the administration of dental anesthesia via the gate control theory.

Objective: To evaluate the effectiveness of the VibraJect® in decreasing intra-oral pain perception during the injection of a local anesthetic in conjunction with dental treatment.

Methods: Forty participants identified during routine dental exams will receive two maxillary intra-oral anesthetic injections. Inclusion criteria include the need for restorative or localized periodontal therapy in bilateral maxillary premolars or molars. The VibraJect® will be attached to the dental syringe for both injections, but will be

activated for only one. The order of administration of the injections will be randomized. Participants will wear blindfolds and headphones during both injections. After each injection, the patient will mark on a visual analog scale (VAS) his perception of pain during the administration of the local anesthesia. After the second injection, the participant will be asked if he could determine which side had the VibraJect® activated. VAS pain ratings will be measured by a metric ruler to the nearest millimeter. Data will be analyzed via the Wilcoxon signed rank test. The percentage of correctly identified VibraJect® injections will also be recorded.

Results: Participants have begun to be enrolled. The goal is to enroll forty participants.

Discussion: Studies on the efficacy of the VibraJect® attachment in reducing dental pain perception during the administration of dental anesthesia have been equivocal. This study was developed to avoid some of the design limitations of previous studies. Participants will serve as their own controls to minimize variables that may affect the study. Every participant will receive an appropriate dose of anesthetic consistent with the standard of care. Participants will be blinded during the execution of the protocol. Finally, only adult participants will be included in the study.

Conclusions: Results of this study may provide additional data that can aid in determining the efficacy of the vibrating dental attachment in reducing pain perception during the administration of local anesthesia.

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1. VAS Visual Analog Scale
2. NPDS Naval Postgraduate Dental School
3. WRNNMC Walter Reed National Naval Medical Center

CHAPTER I: REVIEW OF THE LITERATURE

Dental anxiety and phobia are the two major reasons people avoid seeing the dentist (Bare & Dundes, 2004). Fear of dental injections affects how more than 25% of patients approach dental care; for many, fear may be so severe that they completely avoid seeking dental care (Milgrom & colleagues, 1997).

The terms fear, anxiety, and phobia are sometimes used interchangeably, but they are distinctly different unpleasant emotional states, although they evoke similar changes in physiology (Catherall, 2003). Fear is an unpleasant response to a real, external source of danger, while anxiety is a feeling of apprehension, uncertainty, or fear to imagined or non-identified stimuli. A phobia refers to persistent abnormal and irrational dread or fear associated with aversive behavior towards a specific situation, activity, or object. By definition, people with a phobia are aware that their response is irrational or excessive (Dorland's Illustrated Medical Dictionary, 2011). These emotional states elaborate, in varying degrees, a spectrum of physiological changes: increased heart rate, altered respiration, sweating, trembling, nausea, weakness, or fatigue that make patients exceedingly uncomfortable with dentistry. Since some dental patients do not recognize their severe aversion to the dental appointments as irrational, it has been suggested that such patients may actually be suffering post-traumatic stress disorder induced by previous experiences associated with the dental setting (Bracha, Vega, & Vega, 2006).

Dental injections, in particular, are sources of fear and anxiety for many patients. Dentistry has sought to improve patient experience by multiple efforts that aim to reduce injection induced pain perception. These efforts have brought to market a number of

methods and delivery devices that may help dentists administer local anesthesia in a less painful manner.

Methods to reduce dental pain perception

Dental providers can employ a variety of means to reduce the perception of pain during the administration of local dental anesthetic. Providers can shake the lip while a local dental anesthetic injection is being delivered. This method is thought to be effective due to the gate control theory described by Melzack and Wall (1962), in that lip shaking activates nerves that send non-painful impulses to the brain faster than the nerves activated by a needle prick. Although the efficacy of topical anesthetic is equivocal, many providers routinely use topical anesthesia before the actual injection is initiated (Hutchins, Young, Lackland, & Fishburg, 1997). Providers can also warm buffered local anesthetic solution to help decrease dental injection pain perception (Colaric, Overton, & Moore, 1988). In addition, providers can reduce patient anxiety during dental treatment by administering conscious sedation via medications such as nitrous oxide or a short-acting benzodiazepine. Finally, providers can use mechanical adjuncts that may reduce dental injection pain. These adjuncts are grouped as intraosseous techniques, needleless/jet injections, and vibratactile devices (Ogle & Mahjoubi, 2011).

The X-tip™ (Dentsply Maillefer, Tulsa, OK) (Figure 1) and Stabident™ (Fairfax Dental, Miami, FL) are two intraosseous devices that are indicated for use in specific clinical situations. Each device enables intraosseous injections into the bone around a tooth when profound anesthesia of a "hot" tooth is difficult to achieve by traditional nerve block or tissue infiltration techniques (Ogle & Mahjoubi, 2011). Gallatin and colleagues (2003) found that X-tip™ and Stabident™ produce similar onsets of action,

durations of anesthesia, and increases in heart rate. For both systems, providers insert the needle of the device through the attached gingiva to reach the bone. The main difference between the devices is that the sleeve that guides the X-tip™ into the bone remains in place, simplifying subsequent introduction of the anesthetic needle. Intraosseous devices cannot be used in areas of periodontal disease or in areas with minimal interproximal space (Gallatin & colleagues, 2003). Ogle and Mahjoubi (2011) reported up to 95% success in delivering profound anesthesia to numb "hot" teeth. Intraosseous injections are less successful as a primary technique in providing profound anesthesia of mandibular first molars and have an average reported success rate of 75% (Wong, 2001). Unfortunately, intraosseous injections are quite invasive. They require a gingival perforation or a gingival tissue flap, and then cortical plate perforation so that local anesthesia can be introduced into the alveolar bone (Clark & Yagiela, 2010). Intraosseous injections, as stated above, cannot be used for patients with periodontal disease or limited attached gingiva, and possible complications include increased heart rate, infection at the perforation site, and perceived hyperocclusion (Wong, 2001).

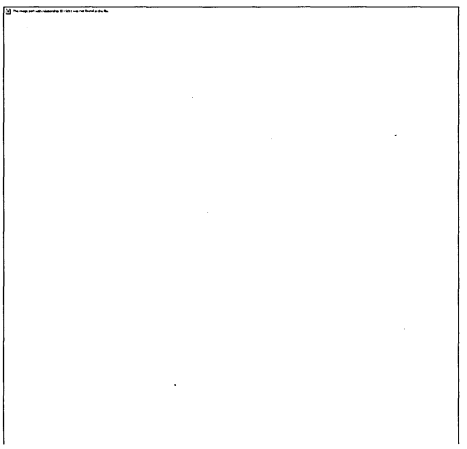


Figure 1. X-tip™ (Dentsply Maillefer) (Midwest Dental website, 2012).

Needleless jet-injection syringe systems were introduced in 1866 and first used for immunizations and vaccines, and were eventually modified for use in dentistry (Wong, 2001). The needleless Syrijet™ Mark II System (Mycone Dental Supply, Cherry Hill, NJ) has been an effective alternative to topical anesthesia for dental applications. Saravia and Bush (1991) reported that the Syriijet™ needleless syringe worked best with pediatric patients. Twenty-five of 34 children preferred the Syriijet™ injection system to a conventional syringe; and in those children, the Syriijet™ successfully provided adequate anesthesia for 36 of 45 dental procedures. However, in a study involving 40 children, when lateral incisors were tested by post-anesthesia pulp tests, only a 13% pulpal anesthesia success rate was achieved (Wong, 2001). The Syriijet™ Mark II System provides rapid onset of anesthesia without the risk of needle stick injuries. Disadvantages include loud noises, pressure sensations, equivocal pulpal anesthesia, and increased chance of hematomas (Wong, 2001).

Presently, four vibratactile devices for injections are available on the market and a fifth device, the Syringe Micro Vibrator, is ready to be introduced. Currently, practitioners can choose the Wand™ (Milestone Scientific, Livingston, NJ) Dental Vibe® (Bing Innovations, Crystal Lake, IL), Accupal™ (Advance Design, Little Rock, AR), or VibraJect® (Irvine, CA) (Ogle & Mahjoubi, 2011; Bonjar, 2011). The Wand™ is a computer-controlled anesthetic delivery system marketed to perform the full scope of traditional injections administered by dentists (Ogle & Mahjoubi, 2011). Its unique appearance compared to the conventional syringe and its computerized control of anesthetic flow via a foot petal (Blanton & Jeske, 2003) may be factors in its advertised ability to allow "painless" injections. However, Kuscu and Akyuz (2008) reported no

significant difference in injection pain perception among 41 children, ages 9-13, who received dental injections by the Wand™ or via the traditional dental injection. With each injection technique, participants who had pre-injection anxiety had higher perceived pain than those who did not have anxiety. Conversely, Blanton and Jeske (2003) reported that 96% of adult participants perceived the Wand™ to be more comfortable than a traditional injection.

In another study of 62 children between the ages of 5 and 13 years, Gibson ,Allen, Hutfless, and Beiraghi (2000) examined how the Wand™ affected disruptive behavior during palatal injections. The children were randomized into two groups to receive either the Wand™ or the conventional dental syringe injection. Children receiving anesthetic with the Wand™ received only palatal injections, while those receiving anesthetic with the conventional syringe received a buccal infiltration and a palatal injection. Pain behavior was coded by the investigators. Also, the children in each group were asked to rate their level of satisfaction with the injection they received compared to previous dental injection experiences. In this study, disruptive behavior observed during the delivery of traditional palatal injections was greater than the disruptive behavior observed during the delivery of palatal injections using the Wand™. For both the investigators' ratings of the children's disruptive behavior and the children's self-reported satisfaction levels, there were no statistically significant differences between the responses during the delivery of palatal injections using the Wand™ and the delivery of traditional buccal injections. Since the disruptive behavior observed by investigators using the Wand™ during a palatal injection was statistically less than that of a traditional palatal injection,

the investigators judged that the Wand™ reduced the likelihood of disruptive behavior during palatal injections.

In a 2009 study by Tahmassebi, Nikolaou, and Duggal, 20 children received buccal infiltration injections via the Wand™, while 18 received traditional local anesthetic infiltrations. Each child received only one injection. With help from their parents, the children marked on a Visual Analog Scale (similar to Appendix A) their perceived pain level associated with their injections. Children were also asked by their providers to choose one of eight pictures on the Venham picture scale (Figure 2) that best described their anxiety during the injection procedure.

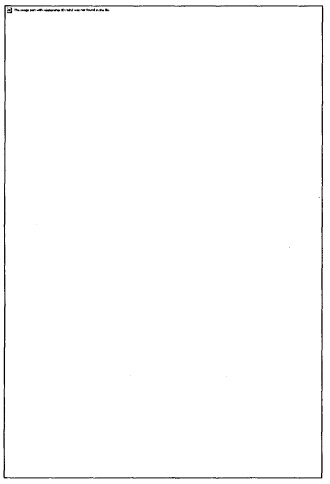


Figure 2. Venham Picture Scale. (Leong & colleagues, 2007). Used with permission from the publisher.

The authors concluded that there was no difference in the pain or anxiety experienced by children anesthetized with the Wand™ compared to that of children anesthetized with conventional injections.

Primosch and Brooks (2002) used the Wand™ to anesthetize 20 adult participants with bilateral palatal injections following the administration of topical anesthesia. One injection utilized a slow flow rate (161 sec/ml), while a rapid flow rate (29 sec/ml) was administered to the opposite side. Each side received 0.3 ml of local anesthetic solution. Patients recorded their pain responses on a VAS, while the operators noted the patient's

heart rate as a physiologic indicator of pain response during anesthesia administration. VAS data revealed that the slow flow rate of local anesthetic delivery was statistically significantly less painful to the participants than the rapid flow rate. However, the authors also reported that the Wand™ did not completely eliminate pain perception.

The Wand™ has several disadvantages. The basic Wand™ unit (Figure 3) costs $1,995, compared to about $25 for a conventional dental syringe, and is not compatible with regular injection needles (Ogle & Mahjoubi, 2011). In addition, disposable needles, handpieces, injection tubing, and anesthetic cartridge holders must also be purchased. With these extra items, the Wand™ generates more hazardous material per injection when compared to injections using traditional aspirating syringes (Ogle & Mahjoubi, 2011).

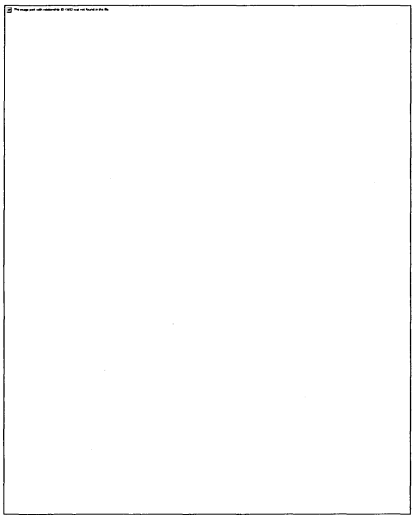


Figure 3. The Wand™ (Milestone Scientific) (Dental Fear Central website, 2012).

The DentalVibe® (Bing Innovation, Crystal Lake, IL) (Figure 3) is an apparatus that vibrates the mucosa while the anesthetic is administered via a conventional dental syringe. The device is held like a pen with one hand while the provider's other hand guides the syringe for the injection . The DentalVibe® costs approximately $795 (Ogle & Mahjoubi, 2011). There are currently no published studies involving this apparatus.

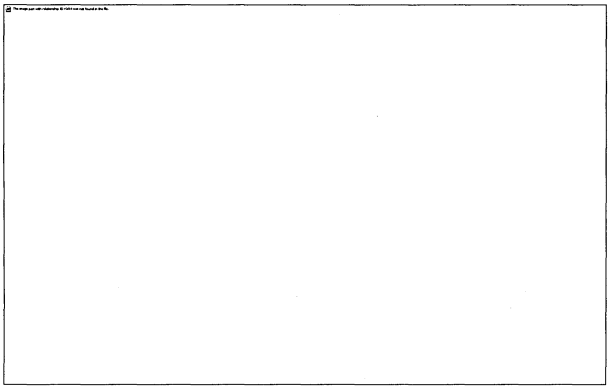


Figure 4. DentalVibe®
(Bing Innovations)
(www.Dexigner.com, 2012).

A third vibrating apparatus is the Accupal™ (Advance Design, Little Rock, AR) (Figure 5). The Accupal™ is a cordless palatal injection system that uses vibration to minimize pain perception via the gate control theory proposed by Melzack and Wall (1962, 1965). This vibration will activate non-nociceptive mechanoreceptors in the mucosa. These mechanoreceptors have a lower activation threshold and may have an inhibitory effect on the nociceptive receptors and thereby, reduce pain perception. The injection needle is placed through the hole in the head of the device to deliver the anesthetic solution. The cost is $499 (Ogle & Mahjoubi, 2011). There are currently no published studies involving this apparatus.

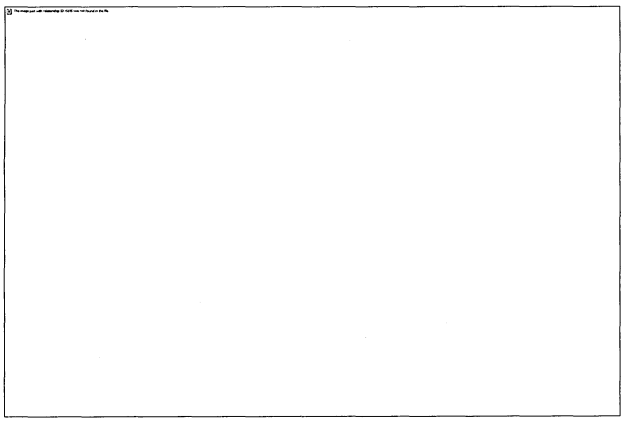


Figure 5. Accupal™
(Advance Design)
(Dental blogs.com, 2012).

The Syringe Micro Vibrator (Iran Patent 63765) (Figure 6) was introduced in 2011 in Iran, but has not been approved for use in the United States (Bonjar, 2011). This device is clipped directly onto the dental aspirating syringe and vibrates the entire syringe

in an attempt to reduce pain perception via the gate control theory (Melzack and Wall, 1962, 1965). No published studies have evaluated the efficacy of this device.

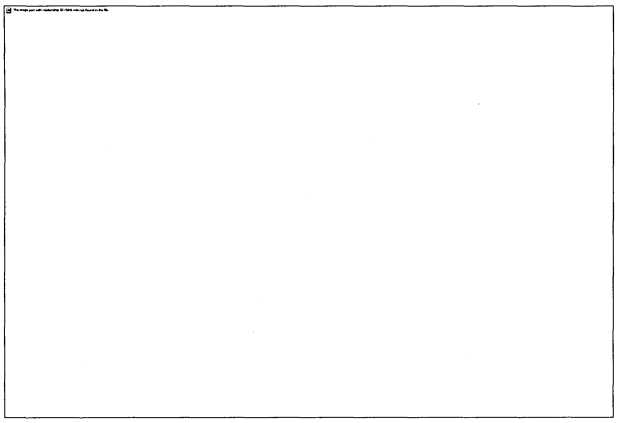


Figure 6. Syringe Micro Vibrator (Iran patent 63765) (Annals of Surgical Innovations and Research, 2012).

A) Posterior-anterior view of SMV, structural components:

a) Stainless steel shell containing motor and eccentrically weighted plate

b) Power switch,

c) Stainless steel cap,

d) Four flexible attachment arms for firm attachment

e) Shell concavity for well adaptation on syringe barrel.

B) Anterior-posterior view of SMV and stainless steel cap bearing button cell batteries

C) SMV is applicable to most standard conventional syringes through four flexible grasping positioning arms and shell concavity

D) SMV mounted on syringe barrel

E) Lateral syringe view indicates that mounting of SMV causes no restriction for the replacement of cartridge.

The VibraJect® (Figure 7, VibraJect LLC, Newport Coast, CA) has been available since 2002. Like the Syringe Micro Vibrator, the VibraJect® is a mechanical vibrating device that is attached to the conventional dental syringe. When activated, the VibraJect® causes the anesthetic delivery needle in the dental syringe (rather than the entire syringe) to lightly vibrate at a frequency of 10,000 cycles per minute. The VibraJect® attachment does not require any changes in operator technique for delivering intraoral local anesthetic injections. The device costs $300 and requires no additional items other than batteries that power the attachment (Ogle & Mahjoubi, 2011).

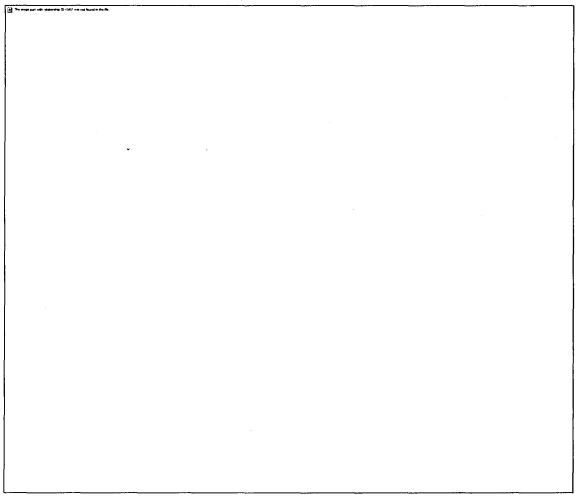


Figure 7. VibraJect® (VibraJect LLC) (Vibraject website, 2010)

The VibraJect®'s mechanism of pain inhibition is attributed to gentle needle vibration and is conceptually based on the principle of the gate control theory of nerve function proposed in 1962 and modified in 1965 by Ronald Melzack and Patrick Wall (Melzack and Wall, 1962, 1965).

Gate Control Theory

According to the gate control theory, pain perception is modulated by the interaction between nociceptive and non-nociceptive afferent neurons. Potential pain

impulses are transmitted to the brain via two types of peripheral nociceptive nerve fibers, the Aδ fibers and C fibers, which are classified by diameter and conduction velocity. Thicker Aδ fibers are myelinated and transmit impulses that are interpreted as sharp pain at 6 to 30 meters per second. Thin C fibers are unmyelinated and carry impulses interpreted as aching or throbbing pain at only 0.5 to 2.0 meters per second. Aβ fibers, a third type of afferent nerve fiber, are non-nociceptive in nature. They are stimulated by touch and vibration, and primarily conduct mechanoreceptive impulses to the brain at 30 to70 meters per second (Melzack & Wall, 1962, 1965). The thresholds of the nerve endings that activate Aβ fibers are also much lower than the thresholds of the nociceptive nerve endings that stimulate Aδ fibers and C fibers.

When both nociceptive and non-nociceptive nerves are stimulated, the faster, lower threshold Aβ fiber input may have inhibitory effects on the firing of Aδ and C fibers. Thus, the Aβ impulses can "close" the gate on Aδ and C fiber impulses of pain (Kandel, Schwartz, & Jessell, 2000). Based on the gate control theory, when a vibrating anesthetic needle pierces tissue, mechanoreceptive (non-nociceptive) Aβ nerve fibers are activated, causing the slower nociceptive nerve pain transmission to be masked. VibraJect® LLC proposes that a conventional dental syringe equipped with an activated VibraJect® will reduce pain perception from an intraoral injection.

Previous VibraJect® Studies

Four studies have evaluated VibraJect®'s efficacy for reducing pain from dental anesthesia injections. Two studies concluded that VibraJect® does not decrease pain perception (Saijo, Ito, Ichinohe, & Kaneko, 2005; Roeber, Wallace, Rothe, Salama, & Allen, 2011), while one study concluded that VibraJect® decreases pain perception

(Terrett, Murray, Hussey, & Lynch, 2005). A fourth study that compared the Wand ™ to the VibraJect® found no difference in injection discomfort between the two systems (Quarnstrom, Bang-Pastore, Woldemichael, & Chen, 2006). Although Quarnstrom and colleagues (2006) concluded that both the Wand ™ and VibraJect® were effective and recommended using them to decrease dental injection pain perception, the authors did not compare the devices to the traditional dental syringe technique.

In a single-blind randomized controlled study (Saijo & colleagues, 2005), five participants received conventional injections and five participants received injections with the VibraJect®. Participants were blindfolded and given headphones prior to all injections. The amount of anesthetic delivered was limited to 0.1 ml of 2% lidocaine with 1:100,000 epinephrine. Participants were asked to evaluate their pain on a 100 mm VAS. The study maintained that the VibraJect® did not produce a statistically significant decrease in pain scores.

Roeber and colleagues (2011) reported a similar conclusion. In a single-blind randomized study, 90 children were divided into two groups. The control group received conventional injections and the experimental group received injections with the VibraJect®. Based on patient self-reports, as well as observations of pain-related disruptive behavior and subjective ratings by the providing dentists, the authors concluded that there was no difference in pain perception between the two groups.

Conversely, Terrett and colleagues (2005) found injections using the VibraJect® to be effective in decreasing perceived pain levels. In this study, 329 adult participants were divided into two groups. One group received a conventional injection; a second group received an injection with the VibraJect® activated. Pain levels were then

recorded on a 10 cm VAS ranging from 0 to 10. The mean pain perception for the VibraJect group was 2.08 (± 0.35) cm compared to 2.68 (± 0.27) cm with the conventional injection. The data also suggested that VibraJect® was most effective when used in anterior intraoral sites where injection pain is perceived to be the most severe (Malamed, 1997).

Quarnstrom and colleagues (2006) found no differences in perceived pain among 36 patients receiving dental anesthesia via the VibraJect® or the Wand™. The authors did not compare the VibraJect® to a conventional injection, stating that there was no way to truly blind the participants to the feeling of the vibration. Prior to the injections, the patients reported their level of apprehension via questions from the examiner. The choices were "calm," "a little nervous," "tense," "afraid," "panicked," and "terrified." Participants were randomly assigned to one of two treatment groups: 19 participants received dental injections using the Wand™ and 17 received injections using the VibraJect®. No topical anesthetic was used in either treatment group. All participants were given 1.8 ml of dental anesthetic. Participants rated the discomfort of the piercing of tissues on a 100 mm VAS. On a second VAS, the participants marked the perceived pain level from the administration and flow of the anesthetic (2% lidocaine with 1:100,000 epinephrine) into the mucosa. On a third VAS, they marked the overall level of discomfort from the entire anesthetic procedure. Results showed no significant differences between the two treatment groups for any of the three VAS measurements. The authors concluded that there was no difference in perceived pain when using the VibraJect® or the Wand™.

Summary

The X-tip™ and the Stabident™ have been used successfully to achieve anesthesia for patients who have difficult clinical challenges whereby conventional technique fails to provide profound anesthesia. However, intraosseous devices are invasive and should be used only if the conventional means of administering anesthesia are unsuccessful.

Melzack and Wall (1962, 1965) described the gate control theory, which contended that pain perception is modulated by the interaction between nociceptive and non-nociceptive afferent neurons. The mechanism of action utilized in vibratactile devices such as the VibraJect® is based on the gate control theory.

The existing studies regarding the effectiveness of the VibraJect® have used varied experimental designs and have produced conflicting conclusions that fail to provide clear evidence about the effectiveness of the device. Saijo and colleagues (2005) used only ten participants, and such a sample size made suspect the statistical analysis to determine differences between the test and control groups. Also, the minimal volume of anesthetic (0.1 ml) administered did not represent a dose typically used for dental treatment (1.0 ml or greater).

Roeber and colleagues (2011) did not compare an activated and non-activated VibraJect® within the same patient. Some patients received an activated VibraJect® injection, while others received the traditionally administered injections. Furthermore, children often could not verbally tell the providers if there was a difference in pain perception, so the pain levels were often subjectively assessed by the dentists administering the injection.

The study by Terrett and colleagues (2005) indicated that operator technique was not calibrated before administering injections. Further, the authors did not indicate how many participants received the VibraJect® and how many did not. Thus, aggregate data may have been skewed to favor either test or control groups.

Quarnstrom and colleagues (2006) did not compare the Wand™ and VibraJect® to the conventional dental syringe technique. The authors stated that there was no way to completely blind the study with the VibraJect® because patients would always feel the vibration on the tissues. They chose to compare the VibraJect® to the Wand™ because the Wand™ vibrates the tissues during the delivery of the local anesthetic and VibraJect® vibrates only the dental needle. Since previous data about the Wand™'s efficacy are equivocal, the authors' conclusion that both the Wand™ and VibraJect® are effective for the delivery of local anesthetic can be questioned, especially since participants did not also receive a conventional injection as a point for comparison.

According to the manufacturer, the VibraJect® reduces pain perception during the delivery of a local anesthetic; however, the existing data do not clearly support that claim. If the VibraJect®, which is a simple and relatively inexpensive attachment to the aspirating dental syringe, is effective in reducing pain perception, providers could use this non-invasive device to decrease patient anxiety and increase patient comfort.

Purpose and Rationale

The previous studies of the VibraJect® had multiple design flaws. This study has been designed to provide data that will allow a more definitive understanding of the VibraJect®'s efficacy as a local anesthetic pain-reducing adjunct. We will enroll a statistically appropriate number of participants (40) to allow for meaningful statistical

analysis. All study participants will need dental treatment on both the right and left sides of their maxillae, either restorative or localized periodontal treatment, which can be accomplished at the same appointment. All participants will receive the same local anesthetic delivery technique (the only difference being an activated versus non-activated VibraJect®) with a five minute pause between injections. All participants will receive a clinically appropriate volume of local anesthetic (1.0 ml) for each maxillary injection and will estimate their pain response on a VAS after each injection. Since participants will be blindfolded and will wear headphones, they will serve as their own controls for estimating pain responses to activated and non-activated VibraJect® injections. This design will minimize the variance concerning pain report that can occur among participants who receive different injections on different days. By recruiting participants from the spectrum of patients who report for dental therapy at WRNMMC Bethesda Dental Clinic and the NPDS Comprehensive Dentistry Clinic, enrolled subjects will represent a diverse group and be in relatively good overall health.

It is well documented that palatal infiltrations, anterior maxillary infiltrations, and mandibular inferior alveolar nerve blocks are more uncomfortable injections than those delivered to other regions of the mouth (Malamed, 1997). However, it is not the aim of this study to further establish that various injections sites in the oral cavity are more painful than others. The aim of this study is to specifically assess, with the fewest variables possible, the ability of the VibraJect® to decrease injection pain by comparing similar treatment sites (non-palatal maxillary right vs. non-palatal maxillary left) in the same participant.

CHAPTER II: MATERIALS AND METHODS

This study is a single-blind randomized clinical trial. Forty active duty patients, identified during their routine annual dental examinations (See Appendix C) at the NPDS Comprehensive Dentistry Clinic or the WRNNMC Bethesda Dental Clinic, who meet the inclusion criteria will be enrolled in the study. The inclusion criteria include:

- Asymptomatic male or female patients with a minimum of at least two similar type teeth needing either restorative therapy or localized periodontal therapy in contra-lateral maxillary quadrants. Teeth may be two bilateral maxillary molars or two bilateral maxillary premolars.
- For teeth requiring restorative therapy due to dental caries, the caries lesions must penetrate the enamel into dentin, but the caries must not have progressed deep enough to involve the dental pulp.
- Localized periodontal therapy is limited to one tooth per maxillary quadrant.
- Medically healthy participants without contraindications for the use of local anesthetics with epinephrine.
- Participants consenting to take part in the study.

The following patients will be excluded:

- Participants who do not have at least two molar teeth or two premolar teeth needing either restorative therapy or localized periodontal therapy in contra-lateral maxillary quadrants.
- Participants with medical conditions that contraindicate the use of local anesthetics (e.g., lidocaine) with epinephrine.
- Pregnant females.

- Participants who do not consent to the study.

Participants who, by the findings of their annual dental l examinations, may meet the inclusion criteria for the study will be given a study brief to read (Appendix B) by the dentist who performs the annual exam. If they are interested in hearing more about the study after reading the brief, an investigator is asked to review the study with the patient.

After consent (Appendix D) has been administered, each participant will receive, within five minutes, two dental injections: one injection with the VibraJect® activated and one with the VibraJect® non-activated. Because participants will receive both types of injections, they serve as their own controls for comparing the pain level caused by each injection. Participants will not be informed which quadrant receives the activated VibraJect® injection.

At the beginning of the dental appointment, the investigator will show each participant how to use the 10-cm visual analog scale (VAS) (Appendix A) to report pain elicited by the local anesthetic injections. A response of zero represents no pain, while a response of ten represents pain as severe as it can possibly be. The side (left or right) of the participant's maxillary arch to receive the VibraJect®- activated injection will be randomly determined by having the dental assistant select one tile out of a closed container. Each tile in the container lists a quadrant (left or right) and a VibraJect® status (activated or non-activated). The tiles specify four possible outcomes: (1) RA = right activated; (2) RN = right non-activated; (3) LA = left activated; (4) LN = left non-activated. The contralateral side will receive the type of injection that was not used during the first injection.

The dental providers involved in the study have been trained with regard to injection technique (Appendix E); the only variable is the use of an activated or non-activated VibraJect® attachment. The VibraJect® is attached to the dental aspirating syringe as illustrated in (Appendix G). The provider will administer the anesthetic solution (1.0 ml of 2% lidocaine with 1:100,000 epinephrine) with a 27 gauge needle as recommended by Malamed (1997). To minimize injection discomfort, needle penetration into the maxillary mucosa will be limited to approximately 3 mm and contact with the periosteum will be avoided. Topical anesthetic will not be used before either injection.

Participants will wear headphones and blindfolds during the administration of both injections. After the first injection, the headphones and blindfolds will be removed and the participants will be asked to rate their pain level on the VAS. The headphones and blindfold will be replaced for administration of the second injection. After the second injection, the headphones and blindfolds will again be removed and participants will be asked to interpret their levels of pain from the second injection on the VAS. After the second VAS interpretation, participants will be asked if they could discern which injection involved the activated VibraJect®. Answering that question concludes the study, and the patient's dentist will then provide the restorative or periodontal dental procedures for both teeth. Treatment appointments will be expected to be completed in less than ninety minutes.

Statistical Analysis

The following data will be analyzed:

1. Two VAS recordings.
    - One after each injection; participants will mark their perceived level of pain

during the administration of each dental anesthetic injection.

2. Percentage of correct identifications of activated VibraJect®.
    - Each participant will be asked to identify which side received the injection with the VibraJect® activated.

The VAS will be measured to the nearest millimeter. Data for the two different injections (Appendix F) will be analyzed via a Wilcoxon Signed Rank Test to determine if there is a statistically significant difference in the perceived pain between the activated and non-activated VibraJect® injections. The non-activated VibraJect® corresponds to the traditional injection approach. The percentage of participants who correctly identify the side with the VibraJect® activated may indicate whether or not participants were effectively blinded. Data will be analyzed using Statistical Package for the Social Sciences (SPSS) Version 18 computer software (SPSS, Inc., Chicago, IL). All statistical significance levels will be set at $\alpha = 0.05$.

Human Subject Use

The protocol for this study was reviewed and approved by the Institutional Review Boards (IRB) for the Walter Reed National Military Medical Center (WRNMMC) and the Uniformed Service University of the Health Sciences (USUHS). All investigators completed the "Collaborative IRB Training Initiative" (CITI) online training to ensure compliance with the requirement for protection of human research subjects.

CHAPTER III: RESULTS

Initiation of this study was delayed due to the illness of the principal investigator and difficulty in finding participants who qualify for the study. To date, one participant has completed the study, and one participant has been enrolled. Two other participants meeting the inclusion criteria have been appointed for consultation and consent, but both failed their scheduled appointments.

A total of 40 participants will be enrolled in the study. Due to insufficient data, no results can be extrapolated at this time. The data from the two visual analog scales were collected and measured. After sufficient data are collected, a Wilcoxon signed-rank test will be performed. In addition, the percentage of participants who correctly identify the side with the VibraJect® activated will be calculated.

CHAPTER IV: DISCUSSION

Changes from Previous Studies

Previous studies of the VibraJect® had multiple design flaws that compromised the validity of their results. Our study sought to avoid these design shortcomings. Unlike the small sample size and clinically irrelevant anesthetic dose reported by Saijo and colleagues (2005), 40 participants scheduled to receive actual dental treatment will receive a clinically appropriate dose of local anesthetic that is consistent with the standard of care doses used when providing dental treatment. As opposed to the Roeber and colleagues (2011) study, only adult patients will be enrolled, and these patients will serve as their own controls since they will have procedures performed on opposite sides of their upper jaws. By randomization, one therapy site will be anesthetized with the VibraJect® activated and the other site will receive anesthesia without the VibraJect® activated. Unlike the study by Terrett and colleagues (2005), we will train all providers so that each participant receives the same technique for injections with and without activation of the VibraJect®. In addition, participants will be blindfolded and wear headphones to ensure patient "blindness" to the type of injection they receive. As opposed to Quarnstrom and colleagues (2006), this study will have participants serve as their own controls to minimize variability of patient experiences with pain. This study will compare patient pain responses after the administration of local anesthesia using an activated VibraJect® versus a non-activated VibraJect® attached to a conventional dental aspirating syringe.

Protocol Rationale

We considered using music in the headphones; however, certain types of music may cause anxiety or annoyance. Suggestions also were made by members of the Institutional Review Board to use sunglasses, rather than blindfolds; however, in a pilot exercise by the investigators, participants were still able to see the dental syringe while wearing sunglasses. Therefore, because the sight of the dental syringe may increase anxiety, we elected to retain the blindfolds. Without blindfolds and headphones, there was no other obvious way to ensure that the study was blinded.

A 27-gauge short needle will be used for all dental injections. The 27-gauge needle was chosen to simplify the protocol because this needle size is commonly used by providers in a typical dental practice. Anecdotally, some providers have suggested that the use of a 30-gauge short needle may result in less patient discomfort. However, Flanagan and colleagues (2007) reported no significant differences in pain perception with dental injections using 25-, 27-, or 30-gauge needles. Three dentists administered 930 injections to 810 adult patients using 25- or 27-gauge needles for mandibular blocks and 25-, 27-, or 30-gauge needles for maxillary buccal infiltrations. The patients were then asked to rate their perceived pain levels on a VAS. No statistically significant differences in perceived pain were found among the dental injections using the three types of needles.

Although many providers use topical anesthetics routinely prior to dental treatment, it is not a standard of care (Ogle & Mahjoubi, 2011). Topical anesthetics may reduce the discomfort of needle insertion when left on the mucosa for at least two minutes (Bhalla & colleagues, 2009; Abu, Andersson & Behbehani, 2005). We chose to

not use topical anesthetic in this study because of the possibility that it might mask the effect of the VibraJect on perceived pain.

The randomization of the VibraJect® activation and order of the local anesthetic delivery were designed to minimize the effect of the memory of the first injection on the response to second injection. It is known that memory of the pain intensity of a previous experience will affect the perceived pain when re-exposed to the same procedure (Gedney & Logan, 2006). Gedney and Logan exposed 43 healthy adult participants to a cold pressor task applied to the forehead, and then re-exposed the participants to an identical cold pressor task nine months later. A baseline VAS pain level was recorded after the initial session. A retrospective pain evaluation was conducted six months after the initial session to assess the memory of the previous pain and its effect on future experience. The recall level of pain at six months for the first session was significantly greater than the actual baseline pain report, but did not significantly differ from the reported pain to the second cold pressor task at nine months. The data suggest that a painful experience modulates how the brain interprets future exposure to an identical stimulus.

Study Limitations

There are several limitations to this study. First, only maxillary infiltration injections will be evaluated. The results may not be applicable to mandibular, palatal, or other block injections because anatomical characteristics in different parts of the mouth vary, and such characteristics can affect the relative pain that injections at different locations produce (Malamed, 1997).

Pre-injection dental anxiety can affect perceived pain (Kuscu & Akyuz, 2008). Thus, participants who have more dental anxiety may perceive greater pain. In this study it would have been interesting to note whether or not dental anxiety or fear influenced pain levels reported following the injections. Adding a pre-injection apprehension score may be useful in future studies to help determine if anxious patients perceive less pain with the vibrating attachment.

Another potential confounding limitation in our study is the possibility for an unequal ratio of males to females since males and females may interpret pain differently. Meechan, Howlett, and Smith (2005) consented 24 volunteers (12 male and 12 females) who each received anterior and posterior palatal mucosa penetrations to periosteum by a 27-gauge short needle attached to a dental cartridge syringe. New needles were used for each injection, and the order of the anterior or posterior needle insertion was randomized. A third penetration was then performed in the maxillary cuspid mucosa using either a new 27 gauge needle or the needle that had been used for the second palatal penetration. Whether a new needle or the previously used needle was employed for the buccal tissue penetration was also determined by randomization. No topical anesthetic or local anesthetic solution was used for any of the three penetrations. Volunteers rated their pain levels on a VAS following each tissue penetration. Women had VAS scores of 32 ± 18 mm and 46 ± 15 mm , while men had scores of 24 ± 12 mm and 45 ± 18 mm, for posterior and anterior palatal injections, respectively. For both women and men, posterior palatal insertions were significantly less painful than anterior penetrations, but no difference in pain perception existed between men and women for either type of palatal injection. However, a gender difference was noted with the buccal insertions, but

only when an old needle was used. Men did not perceive any difference in discomfort during buccal penetration with either a new needle (27 ± 19 mm) or a previously used needle (28 ± 22 mm). Females reported a VAS of 29 ± 18 mm for a new needle used for buccal infiltration, but 41 ± 23 mm for a previously used needle. The authors concluded that females were able to detect the difference between fresh and used needles used for buccal infiltrations, while males were not. Thus, females may feel more discomfort for needles used for more than one injection site. Our study is not using new needles for the second injection and may have an unequal distribution of male and female participants.

Some people are anxious or afraid of the anesthetic or numbness sensation produced by local anesthesia. In a survey of 1500 Australian adults by Armfield and Milgrom (2011), 46% of the respondents rated themselves as anxious about the numbness associated with dental anesthesia. Following fear of needles or injections reported by 75% of respondents, fear of numbness was the second-most reason listed by participants as to why they fear or avoid dental treatment. Our study did not ask the participants whether they are afraid of numbness. Fear of the numbness sensation could affect the perception of pain in this study.

Our study will employ five dentists in the delivery of anesthesia via activated and non-activated VibraJect®. Even though they have been trained to administer the anesthetic in the same manner for this study (Appendix E), there is no way to ensure that each dentist will follow this procedure precisely for every patient. However, since the same dentist administers both injections during the same appointment for each patient, individual study participants should be exposed to minimal variation in injection technique.

Even though participants will wear blindfolds and headphones, they may still be able to feel the vibrating needle within the tissues. Quarnstrom and colleagues (2006) believed this to be true, although they made no attempt to confirm this phenomenon. Rather, they thought it was more clinically relevant to compare two vibrating devices (VibraJect® and the Wand™) than to compare either device with a conventional anesthetic syringe. However, comparing the VibraJect® to the Wand™ did not provide data about how VibraJect® compares against the traditional local anesthetic syringe technique. Our results may provide this information. Moreover, by asking participants directly if they were able to perceive any vibration during the injections, we may be able to answer this question, as well.

We did not measure or account for injection pressure in this study. Kudo (2005) concluded that there is a positive correlation between injection pressure and intensity of pain. In this double-blinded study, 28 healthy male volunteers received 0.5 ml of a local anesthetic solution (2% lidocaine) delivered using a 30-gauge needle via the Wand™, with an injection speed of either 30 or 160 seconds per milliliter. Injection pressure was measured by a standardized sphygmomanometer. Pain and anxiety were assessed with a VAS and Faces Anxiety Scale, respectively. With the Faces Anxiety Scale, the volunteers are shown a series of five facial expressions as a spectrum of increasing anxiety. The first face signifies no anxiety. The next three faces show increasing anxiety levels. The last face signifies the most anxiety. A score of 0 is given if the volunteer points to the face that is not anxious, while a score of 4 is given for the most anxious face. Scores of 1, 2, and 3 were given for the middle faces showing increasing anxiety (Kudo, 2005; McKinley, Stein-Parbury, Chehelnabi, & Lovas, 2005). The results

showed that increased injection pressure elicited increased perceived pain. Up to pressures of 306.99 mm Hg (mercury), the pain levels were low to moderate (defined as scores less than 6 cm on the VAS). Injection pressures higher than 306.99 mm Hg induced VAS pain perceptions in the severe range (defined as scores 6 cm or greater). The Faces Anxiety Scale allows clinical judgments about mood based on non-verbal behavioral responses to a series of structured questions (Kudo, 2005). Injection pressures higher than 363.44 mm Hg produced a score of three on the Faces Anxiety Scale, which suggested a high level of anxiety. Kudo concluded that a positive correlation existed between injection pressure and perceived pain and anxiety.

Identifying and enrolling forty patients who meet the inclusion criteria to participate in this study has been challenging. The majority of patients in the WRNMMC Bethesda Dental Clinic are healthy adults between the ages of 18 and 55 with minimal restorative needs. Perhaps the inclusion criteria (i.e., asymptomatic patients; bilateral maxillary teeth needing either restorative or localized periodontal therapy) were too restrictive for this population. A better location for recruitment might be a dental school or a military recruit training center. These facilities would have larger patient populations with greater treatment needs. Asymptomatic patients were chosen since symptomatic patients present more challenges in achieving anesthesia (Ogle & Mahjoubi, 2011). Moreover, since different areas of the mouth have different anatomical obstacles that may impede dental injections (Meechan & colleagues, 2005), we decided to limit our study to bilateral injections of similar teeth (premolars to premolars or molars to molars). Only maxillary posterior teeth were chosen because infiltrations of the mucosa of the maxillary bicuspid and molar areas are perhaps the easiest locations within the mouth for

administering local anesthesia. As a result of these restrictions, however, our results may not apply to the delivery of local anesthesia to maxillary anterior teeth, mandibular teeth or palatal structures.

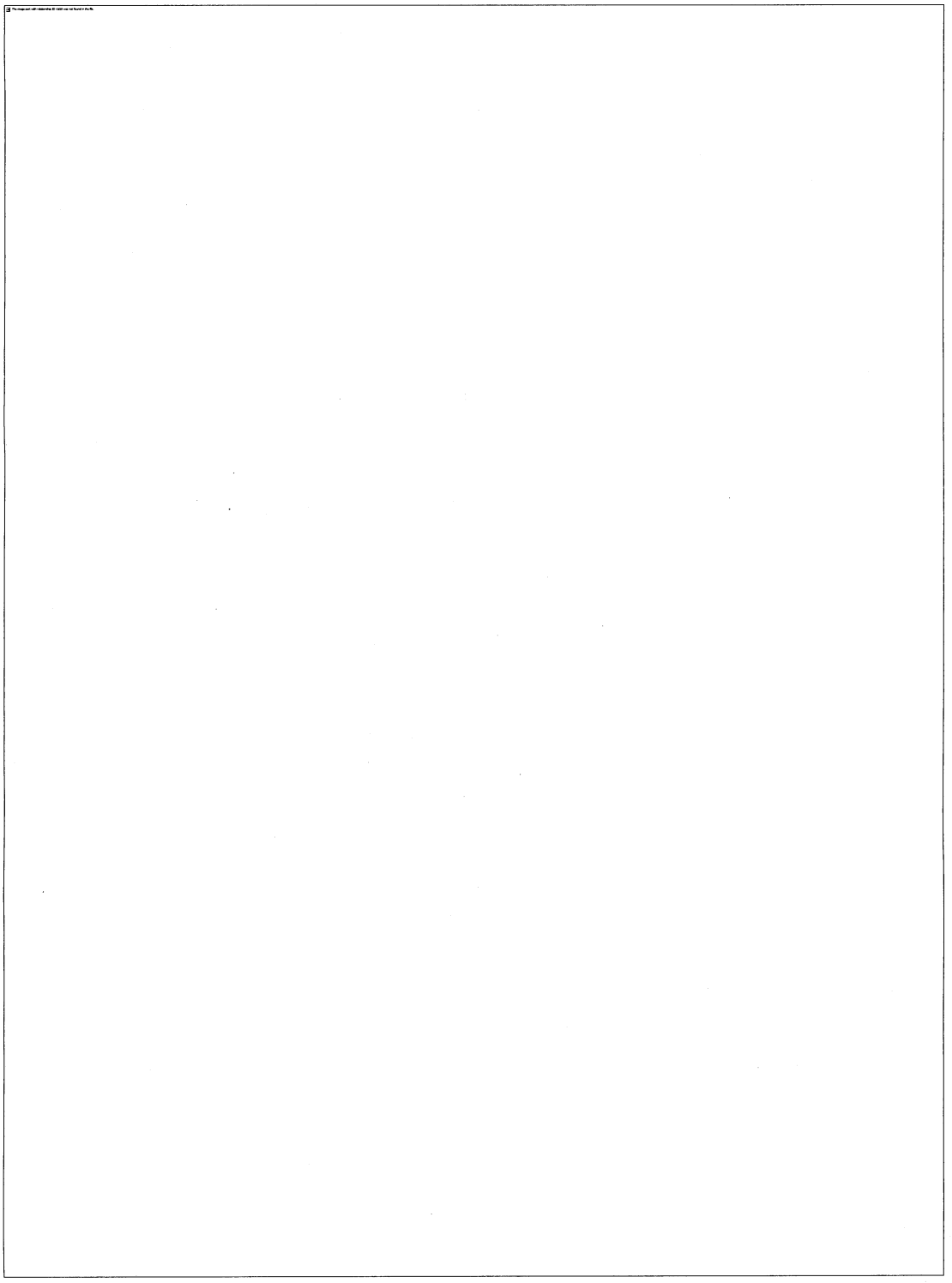
CHAPTER V: CLINICAL IMPLICATIONS

Dental pain perception is influenced by a variety of factors such as gender, pre-injection anxiety, speed, force of anesthetic flow, fear of dental needles and the numbness sensation. Milgrom and colleagues (1997) reported that 25% of dental patients fear the dental injection and may avoid going to the dentist because of this fear. Many people also develop dental fear and anxiety because of past traumatic experiences in the dental office (Bracha & colleagues, 2006; Milgrom & colleagues, 1997). Consequently, fear that makes people avoid the dentist can adversely affect both their long-term dental and overall medical health.

Discomfort during the dental injection is one common cause of dental fear and anxiety (Bracha & colleagues, 2006; Milgrom & colleagues, 1997). If a reliable device that mitigates dental injection pain can be demonstrated to the public, then apprehensive patients may be more likely to seek dental treatment. If the VibraJect® is shown to be effective in reducing perceived dental pain, providers can use this simple non-invasive device to improve patient comfort and reduce patient anxiety. The VibraJect® is compatible with all aspirating dental syringes. If effective, it can be an economical method to reduce dental pain perception.

No definitive conclusions can be established from the limited data collected to date. After data collection and analysis are completed, some conclusions may be evident regarding the efficacy of the VibraJect®. If the VibraJect® is deemed effective in reducing pain perception, this device could be a valuable adjunct to make the delivery of dental anesthesia by injection more comfortable and thus reduce some of the fear and anxiety associated with dental treatment.

APPENDIX A



APPENDIX B

Local Anesthesia Study Brief

You just received a dental exam identifying that you need localized periodontal (gum) disease or restorative dental treatment on both the left and right sides of your upper jaw. The dental treatment that you need can be provided in one dental appointment visit. The Naval Postgraduate Dental School is conducting a research study to see if the discomfort from numbing the teeth for dental treatment can be improved. Your dental treatment fits the criteria of this study. Therefore, you are invited to consider participating in the study.

Whether or not you wish to participate in the study, your dental treatment will be virtually identical. You will receive an appointment during which the treating dentist will numb with local anesthesia each tooth, and provide the necessary treatment. The difference, if you elect to participate in the study, is that the numbing injections will be applied slightly differently, and you will be asked to rate the amount of discomfort associated with each injection. The slightly different numbing technique uses the same dental syringe as used in the regular numbing injection, but has a Food and Drug Administration (FDA) approved attachment that is advertised to reduce dental injection discomfort. This study is designed to see if the FDA approved attachment really helps compared to the usual numbing technique.

This study presents no additional risk beyond that associated with a regular dental appointment for the treatment you need. If you choose to participate, your dental appointment will take about 90 minutes, and both procedures (right and left sides) will be completed. If you decide not to participate in the study, your appointment will be scheduled for 60 minutes (our standard appointment length), you will still receive a numbing injection, and your dental treatment will be provided in the same manner; however, it is possible that only one side, rather than both, will be completed. If so, you will be offered a second appointment on another day to complete your treatment. All appointments will be in the WRNMMC Primary Care Dentistry Clinic or the NPDS Comprehensive Dentistry Clinic.

There is no direct benefit to you for participating in this study. However, if we find that this device is successful, your participation will have helped future patients experience more comfortable dental anesthetic injections. If you are interested in participating or would like more information before making a decision, your examining dentist will have an investigator meet you to thoroughly explain the study. You may decline to participate at any time and make your dental appointment. If you elect to participate, your involvement will help us understand if a simple modification makes dental care more comfortable.

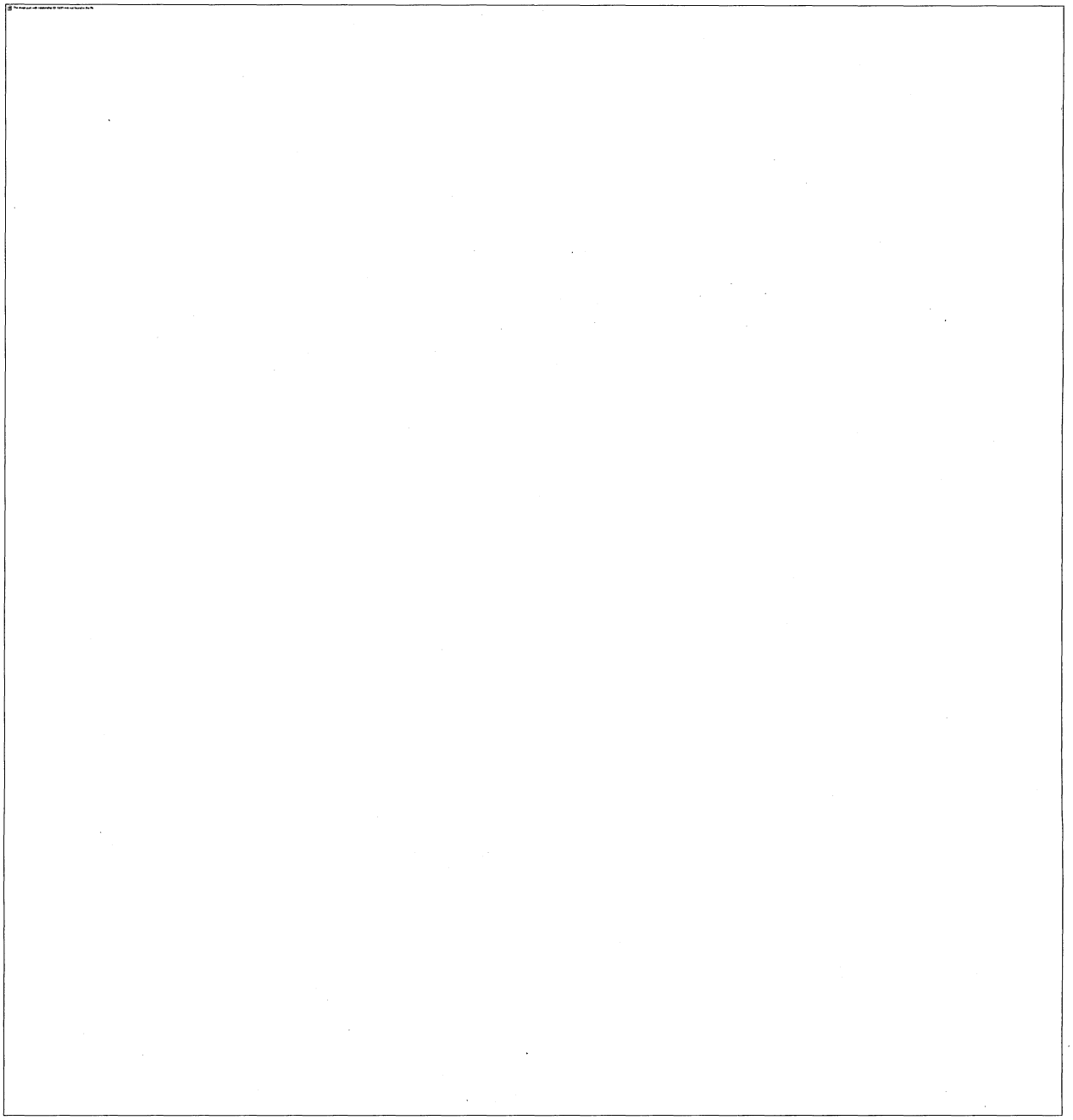
Thank you for your consideration.

POC: Khon Lien LCDR, DC, USN
Phone: 301-319-4821
Comprehensive Dentistry Department
8901 Wisconsin Avenue

Bethesda, MD 20889

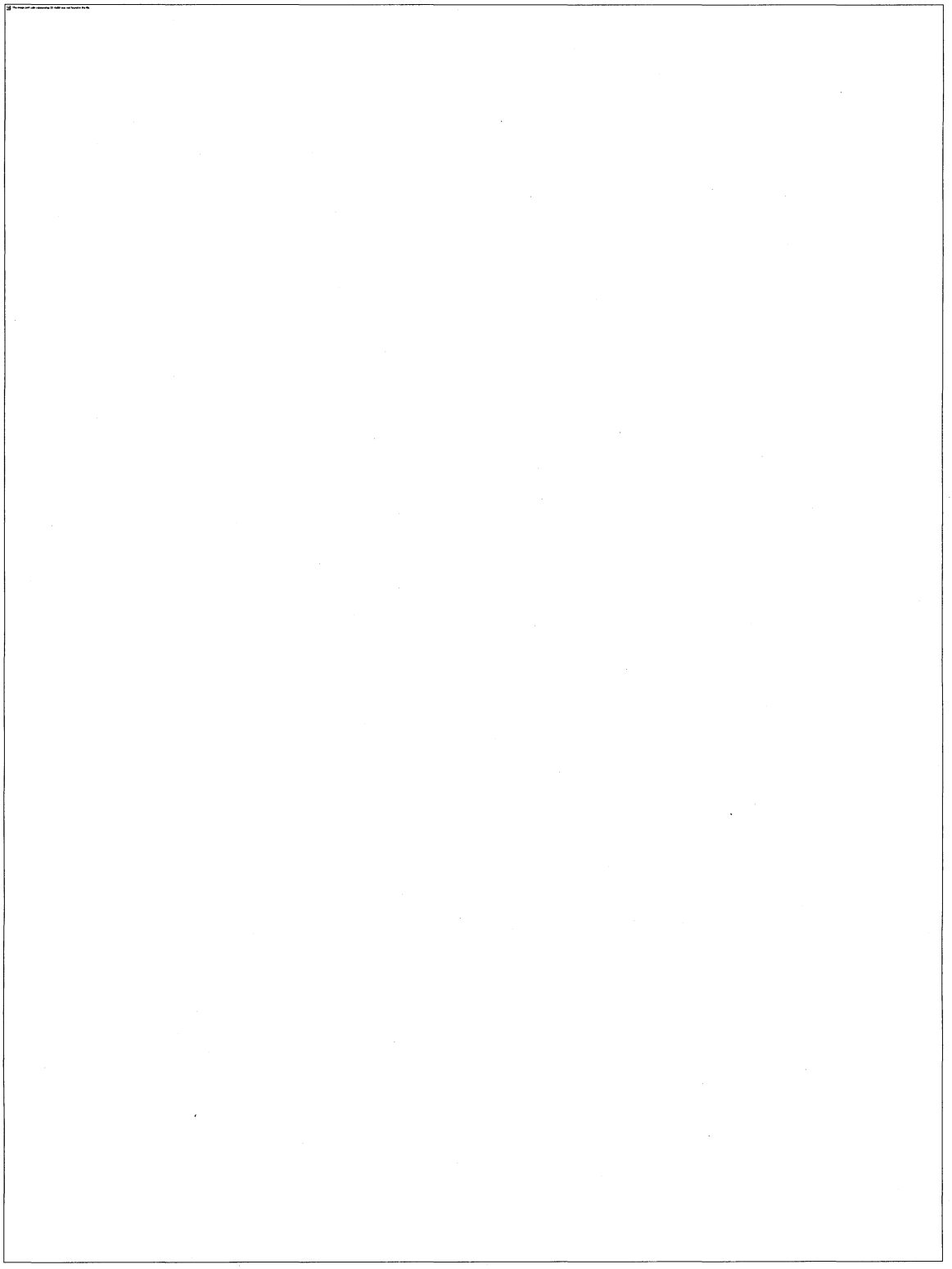
Appendix C

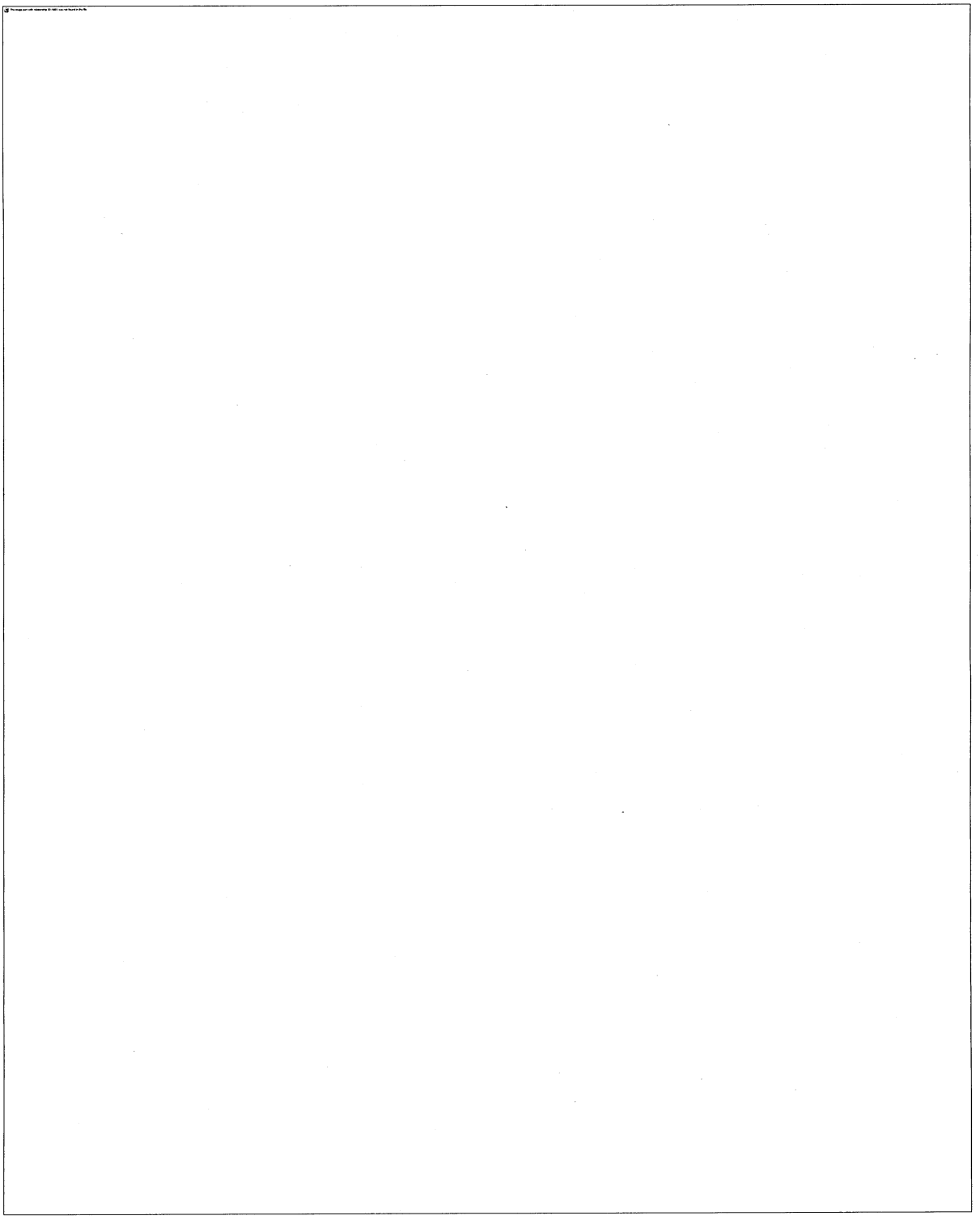
Enrollment Flow Chart

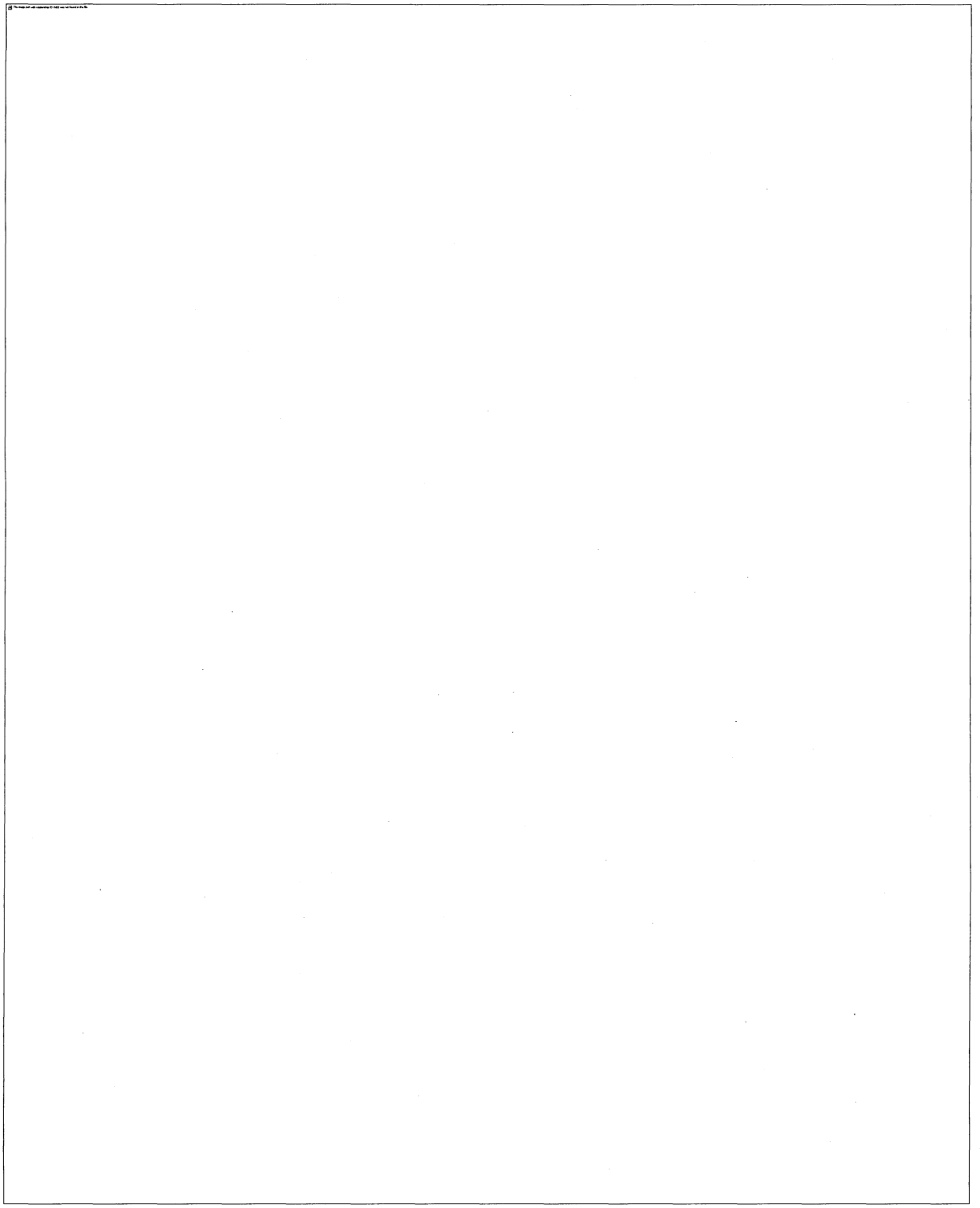


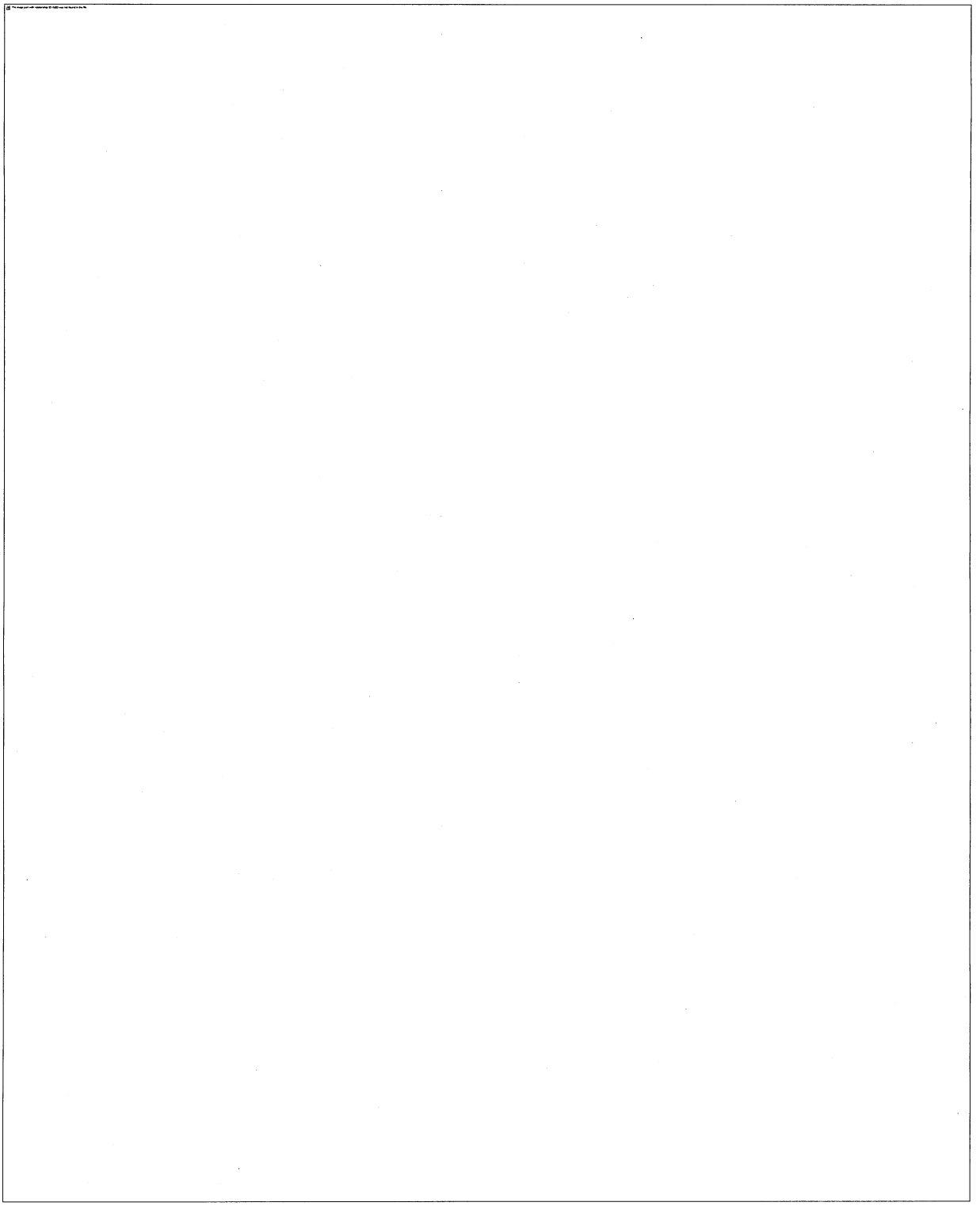
Appendix D

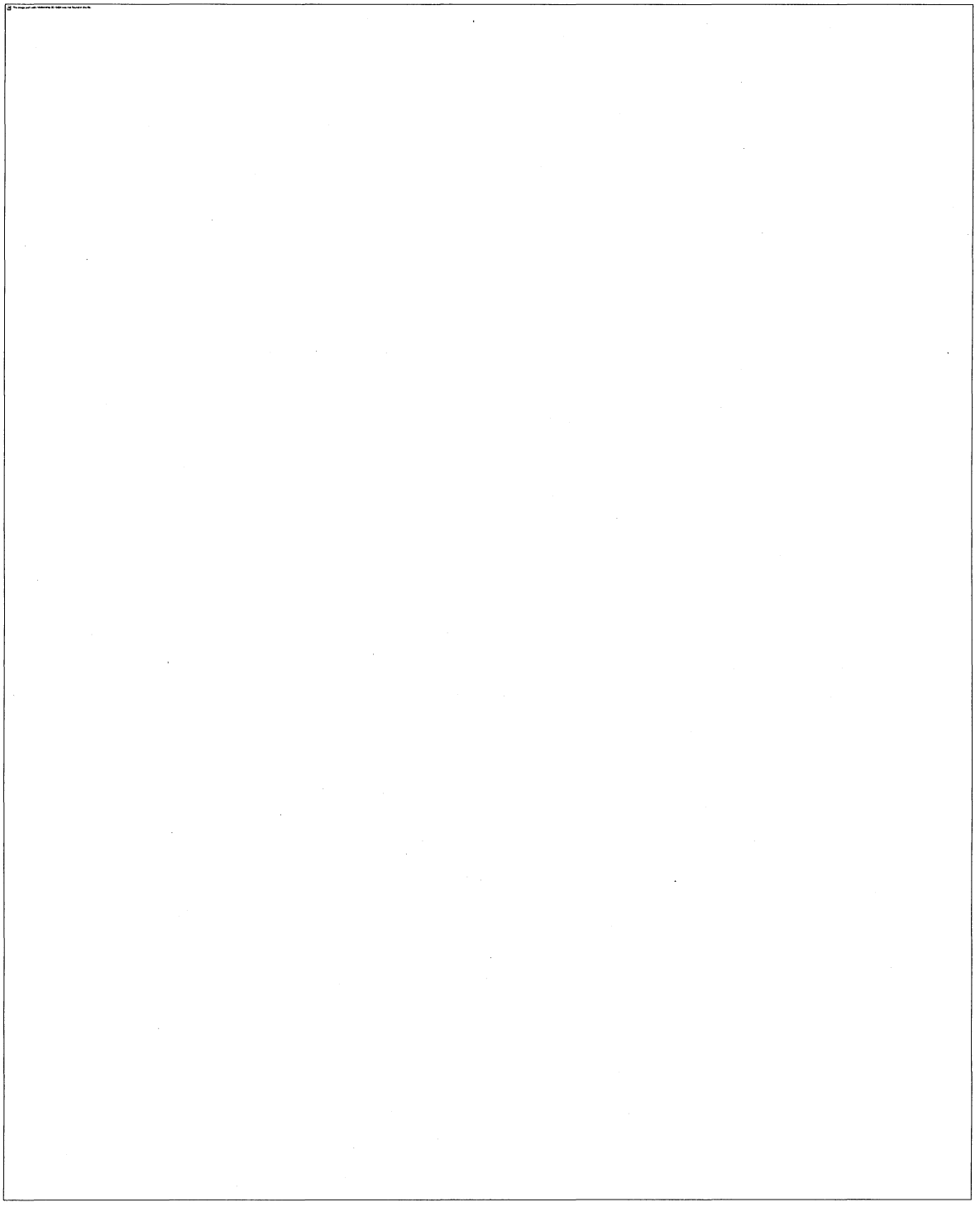
Consent/HIPAA FORM

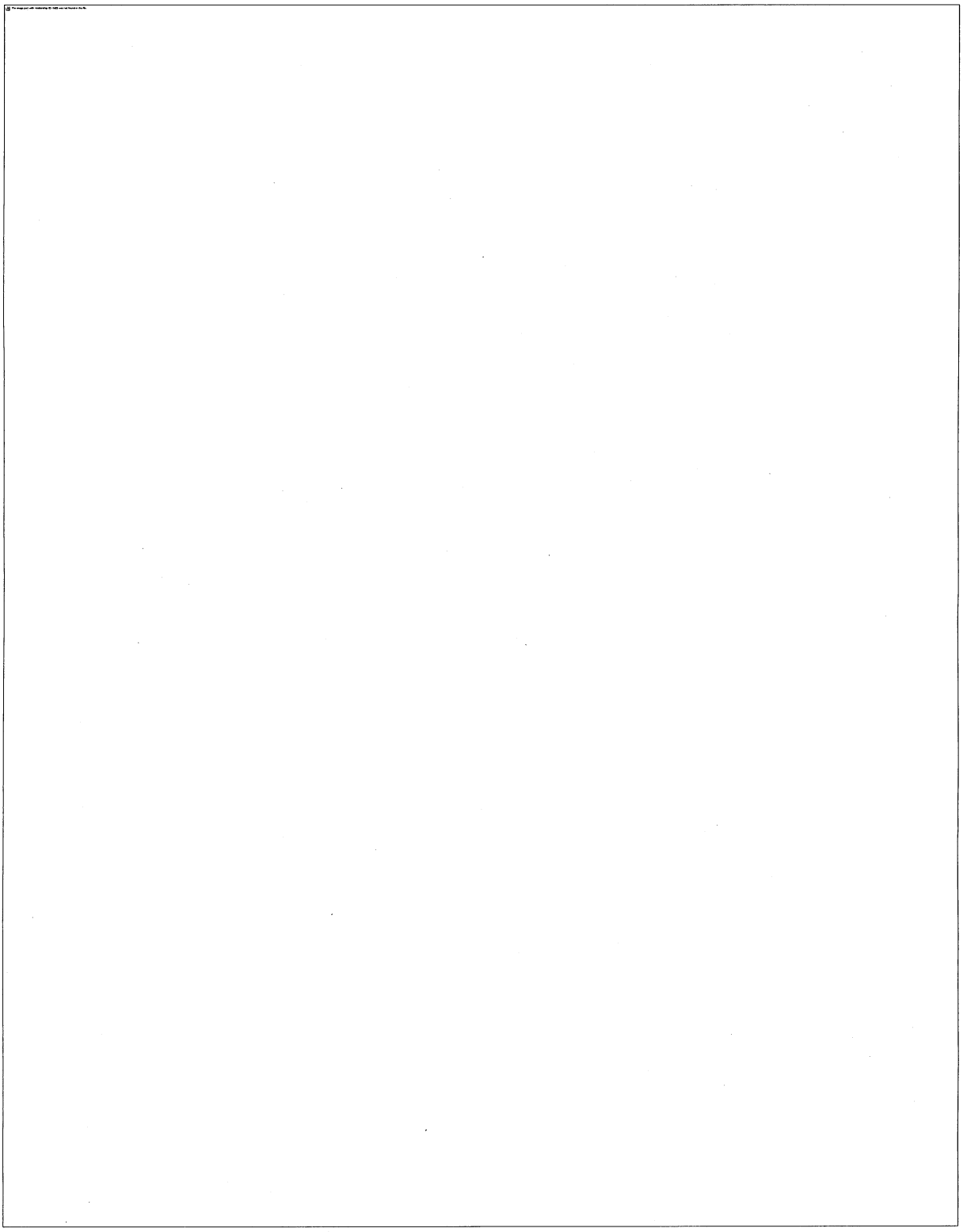












Appendix E

Anesthesia Administration
Protocol for Providers

1. Obtain a signed consent from the participant on the day of the appointment.
2. Verify that the planned restorative or periodontal therapy needs to be completed.
3. Verify that both teeth to be treated are either maxillary molars or maxillary premolars.
4. Place the blindfold and headphones on the patient.
5. Headphones will not have music, only noise cancelling.
6. Select tiles to determine which side will be anesthetized first and whether the VibraJect® is activated or not.
7. Do not use a topical anesthetic prior to anesthetic injection.
8. Do not use any distraction techniques (e.g., shaking the patient's lip, etc.) while administering the anesthetic.
9. Do not use a purchase point on any part of the mouth. A light finger rest for hand stability is acceptable.
10. Administer the anesthetic solution (1.0 ml of 2% lidocaine with 1:100,000 epinephrine) with a 27 gauge short needle per side.
11. To minimize patient discomfort, limit needle penetration into the maxillary mucosa to approximately 3 mm and avoid contact with the periosteum.

Appendix F

Data Collection Sheet

Legend

Site: Location of injection, tooth number and right (R) or left (L) side

Type: Which injection, not activated (N) or activated VibraJect (A)

VAS: Visual analog scale numerical pain rating

Opinion: The patient's opinion as to whether the first (F) or second injection (S) had the VibraJect activated or unknown (U).

	First Injection			Second Injection			Patient
Subject Number	Site	Type	VAS	Site	Type	VAS	Opinion
1.							
2.							
3.							
4.							
5.							
6.							
7.							
8.							
9.							
10.							
11.							
12.							
13.							
14.							
15.							
16.							
17.							
18.							
19.							
20.							

Data Collection Sheet

Legend

Site: Location of injection, tooth number and right (R) or left (L) side

Type: Which injection, not activated (N) or activated VibraJect (A)

VAS: Visual analog scale numerical pain rating

Opinion: The patient's opinion as to whether the first (F) or second injection (S) had the VibraJect activated or unknown (U).

	First Injection			Second Injection			Patient
Subject Number	Site	Type	VAS	Site	Type	VAS	Opinion
21.							
22.							
23.							
24.							
25.							
26.							
27.							
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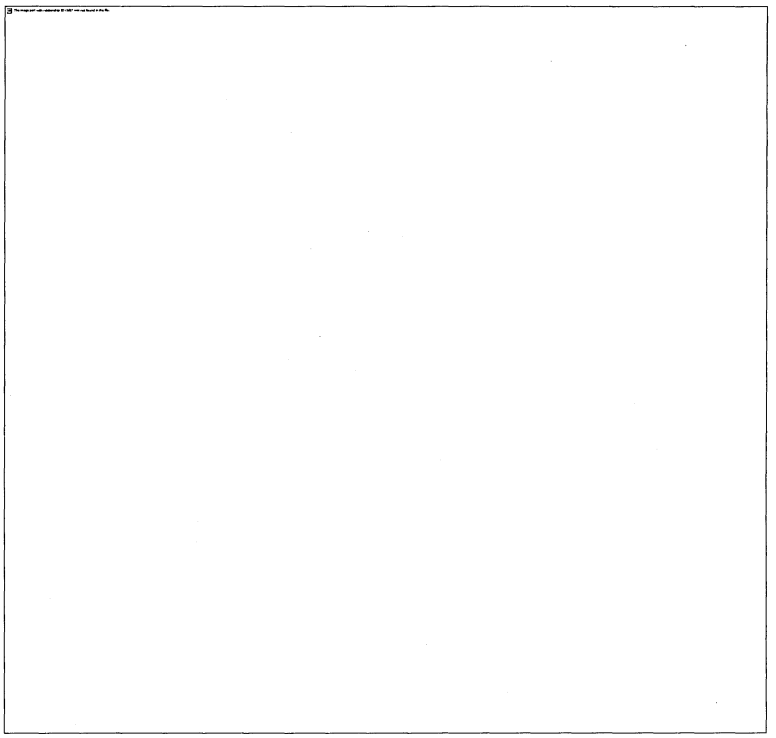
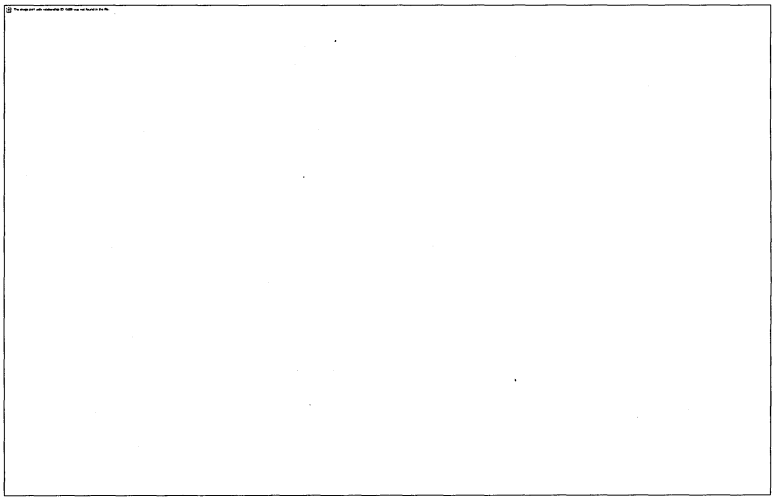
APPENDIX G

Illustration of the VibraJect®





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CERTIFICATE OF APPROVAL

MASTER'S THESIS

This is to certify that the Master's thesis of

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has been approved by the Examining Committee for the thesis requirement for the Master of Science degree in Oral Biology at the June 2012 graduation.

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